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| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO |
|----------------|-------------|----------------------|--------------------|-----------------|
| 09 220,691 | 12 28 1998 | NAOKO TSUJI | 0327-0759-0 | 3088 |

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EXAMINER

WEBER, JON P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

DATE MAILED: 08 09 2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/220,691

Applicant(s)

TSUJI ET AL.

Examiner

Jon P. Weber, Ph.D.

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,3,4 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 26,27.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 01 February 2002 has been entered.

Status of the Claims

Claims 1, 3-4 and 6 have now been presented for examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-4 and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,375,948. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

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instant claims are a species of the genus of the patent claims. The patent claims provide for a method of inhibiting hair growth with a composition comprising 1) inhibitors of elastase-like enzymes or neutral endoproteases and 2) a water or alcohol extract of *Juniperus* or wheat or barley malt. The instant claims are drawn to a method of inhibiting hair growth with a composition comprising inhibitors of elastase-like enzymes or neutral endoproteases.

A double patenting rejection is appropriate despite the filing date of 6,375,948 being after the instant application because this ensures that the conflicting patent and instant application remain commonly owned. There is no question of unjustified or improper timewise extension.

Claims 1, 3-4 and 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,171,595. Although the conflicting claims are not identical, they are not patentably distinct from each other because compounds and plant extracts in the conflicting patent inherently inhibit elastase-like enzymes.

It is admitted at page 2 of the response of 01 February 2002 that Suzuki et al. (US 6,075,052) and Suzuki et al. (US 6,171,595) disclose at least one compound and at least one plant extract that is an inhibitor of elastase-like enzymes is noted. However, the conflicting compounds and extract were not further identified. It can be seen that several of the compounds in column 7 of Suzuki et al. (US 6,171,595) fall within the scope of compounds disclosed instantly at pages 5-6 of the specification to be inhibitors of elastase-like enzymes. Further, extracts of hydrolyzed almond, *Sanguisorba officinalis* (burnet), clove, *rosae multiflorae fructus*, and hawthornis have been shown to be inhibitors of elastase-like enzymes (Moriwaki et al., JP 2969451). Although neither of Suzuki et al. (US 6,075,052) and Suzuki et al. (US 6,171,595)

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qualifies as prior art under 102(a), (b) or (e), a double patenting rejection is appropriate because this ensures that the conflicting patent and instant application remain commonly owned.

Claim Rejections - 35 USC § 112

Claims 1, 3-4 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibitors of elastase-like enzymes, does not reasonably provide enablement for inhibitors of elastase like enzymes or neutral endoproteases that are not inhibitors of a matrix metalloproteinase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

Sundeen et al. (US 4,327,111) disclose the same mercaptopropionamide derivatives that are disclosed instantly at page 7-9 (it is equivalent to JP 57024354 cited therein). These compounds are said to be collagenase inhibitors. Collagenase is generally considered and shown in Sundeen et al. (US 4,327,111) to be a matrix metalloproteinase. Hence, it is not clear how the instant claims can assert inhibiting hair growth with inhibitors of elastase-like enzymes or neutral endoproteases that are not inhibitors of a matrix metalloproteinase and not provide any exemplification of a single compound that meets this limitation.

Other references cited by examiner but not relied upon are cited to establish the state of the art. Wakimasu et al. (US 5,330,978) is equivalent to JP-05105698 disclosed at pages 5-6 of the instant disclosure to be the same phosphonic acid derivative inhibitors of elastase-like

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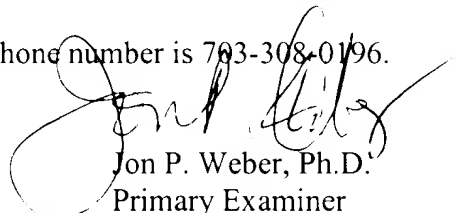
enzymes. Wakimasu et al. (US 5,330,978) does not suggest that these compounds can be used to inhibit hair growth.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P. Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P. Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
August 6, 2002